4014.10-1 Draft Proposed Amendment 2 PATENT

In the Claims:
1-4 (cancelled)

5. (Currently Amended) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein
the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby
elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration;
and

a responsive device coupled to the at least one electrode, the responsive device being
configured to respond to information sensed by the sensor by controlling electrical
stimulation delivered to the tissue through the at least one electrode The device of claim 1
wherein the sensor is configured to sense and the responsive device is configured to
determine information corresponding to a patient's inspiration rate.

6. (Currently Amended) The device of claim 1. A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response:

a sensor configured to sense information corresponding to the patient's respiration; and

a responsive device coupled to the at least one electrode, the responsive device being

configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode:

wherein the sensor is configured to sense and the responsive device is configured to determine information corresponding to a patient's exhalation rate.

7-43 (cancelled).

3

PATENT

44. (Currently Amended) The device of claim 43 A device for managing treatment of a patient comprising:

an implantable sensor configured to sense information corresponding to the patient's respiration:

an implantable memory device coupled to the sensor configured to store the information sensed;

a telemetry device coupled to the memory device configured to communicate the information stored in the memory to an external device; and

an external device configured to upload information from the memory device; wherein the external device is configured to track patient activity compliance.

- 45. The device of claim 44 wherein the external device includes a patient interface configured to receive patient input concerning patient activity compliance.
- 46. The device of claim 45 wherein activity compliance comprises drug treatment compliance.
- 47. (Currently Amended) The device of claim 43-A device for managing treatment of a patient comprising:

an implantable sensor configured to sense information corresponding to the patient's respiration;

an implantable memory device coupled to the sensor configured to store the information sensed;

a telemetry device coupled to the memory device configured to communicate the information stored in the memory to an external device; and

an external device configured to upload information from the memory device, wherein the external device is configured to recommend patient activity based on information uploaded from the memory device.

| 10-1 Draft Proposed Amendment 4 | PAIDNI |
|--|-----------------------------|
| 18. The device of claim 47 wherein the recommended patient activity is a lrug regimen. | recommended |
| 19. (Cancelled) | |
| | |
| 50. (Currently Amended) The device of claim 49 44 wherein the communication to a home to communicate patient activity compliance information to a home | |
| 51-51 (Cancelled) | |
| 33. (Currently Amended) The device of claim 51 A device for managing a | respiration of a |
| patient comprising; | |
| at least one electrode configured to be coupled to tissue of a patien | t's body wherein |
| he at least one electrode is configured to deliver electrical stimulation to t | <u>he tissue to thereby</u> |
| elicit a diaphragm respiratory response; | |
| a sensor configured to sense information corresponding to the patie | ent's respiration. |
| wherein said sensor is configured to sense respiratory response; and | |
| a programming device configured to adjust stimulation parameters | to elicit a desired |
| espiratory response; | |
| wherein said electrical stimulation comprises a burst of pulses and | wherein the |
| programming device is configured to adjust frequency of the pulses. | |
| 54. (Currently Amended) The device of claim 51 A device for managing | respiration of a |
| patient comprising: | |
| at least one electrode configured to be coupled to tissue of a patien | t's body wherein |
| he at least one electrode is configured to deliver electrical stimulation to t | he tissue to thereby |
| elicit a diaphragm respiratory response; | |
| a sensor configured to sense information corresponding to the patie | ent's respiration, |
| wherein said sensor is configured to sense respiratory response; and | |
| | |

| 4014.10-1 | Draft Pro | posed Amendment | 5 |
|-----------|-----------|-----------------|---|
|-----------|-----------|-----------------|---|

PATENT

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein said electrical stimulation comprises a burst of pulses and wherein the programming device is configured to adjust pulse width of the pulses.

| 55. (Currently Amended) The device of claim 51 A device for managing respiration of a |
|---|
| patient comprising: |
| at least one electrode configured to be coupled to tissue of a patient's body wherein |
| the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby |
| elicit a diaphragm respiratory response: |
| a sensor configured to sense information corresponding to the patient's respiration, |
| wherein said sensor is configured to sense respiratory response; and |
| a programming device configured to adjust stimulation parameters to elicit a desired |
| respiratory response: |
| wherein said electrical stimulation comprises a burst of pulses and wherein the |
| programming device is configured to adjust duration of the pulses. |
| 56. (Currently Amended) The device of claim 51 A device for managing respiration of a |
| patient comprising: |
| at least one electrode configured to be coupled to tissue of a patient's body wherein |
| the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby |
| elicit a diaphragm respiratory response: |
| a sensor configured to sense information corresponding to the patient's respiration, |
| wherein said sensor is configured to sense respiratory response; and |
| a programming device configured to adjust stimulation parameters to elicit a desired |
| respiratory response; |
| wherein the programming device is configured to adjust stimulation to control tidal |
| volume of a respiratory cycle. |

| 4014.10-1 Draft Proposed Amendment | 6 | PATENT |
|---|--------------------------------|---|
| 57. (Currently Amended) The device of | claim 51 A d | evice for managing respiration of a |
| patient comprising: | | |
| at least one electrode configured t | o be coupled | to tissue of a patient's body wherein |
| the at least one electrode is configured to | deliver electr | ical stimulation to the tissue to thereby |
| elicit a diaphragm respiratory response: | | |
| a sensor configured to sense infor | mation corres | ponding to the patient's respiration, |
| wherein said sensor is configured to sensor | <u>e respiratory r</u> | esponse; and |
| a programming device configured | to adjust stim | ulation parameters to elicit a desired |
| respiratory response; | | |
| wherein the programming device | is configured | to adjust stimulation to control |
| inspiration rate. | | |
| 58. (Currently Amended) The device of | claim 51 <u>A d</u> | evice for managing respiration of a |
| patient comprising: | • | |
| at least one electrode configured t | o be coupled | to tissue of a patient's body wherein |
| the at least one electrode is configured to | deliver electr | ical stimulation to the tissue to thereby |
| elicit a diaphragm respiratory response; | | |
| a sensor configured to sense infor | mation corres | ponding to the patient's respiration, |
| wherein said sensor is configured to sensor | e respiratory r | esponse: and |
| a programming device configured | d to adjust sti | mulation parameters to elicit a desired |
| respiratory response; | | |
| wherein the programming device | is configured | to adjust stimulation to control |
| exhalation rate. | | |
| 59-65 (cancelled) | | |
| 66. (Currently Amended) A method of c | ontrolling the | respiration of a patient comprising |
| the steps of: | | |
| sensing information corresponding | | |
| subsequently sensing information | correspondin | g to respiration of the patient; |

PATENT

determining whether to electrically stimulate the tissue to elicit a diaphragm response in the patient: The method of claim 64 further comprising the steps of

sensing resumption of <u>said</u> intrinsic breathing in a patient after electrically stimulating the tissue to elicit the diaphragm response; and ceasing electrical stimulation after sensing resumption of <u>said</u> intrinsic breathing.

67. (Cancelled)

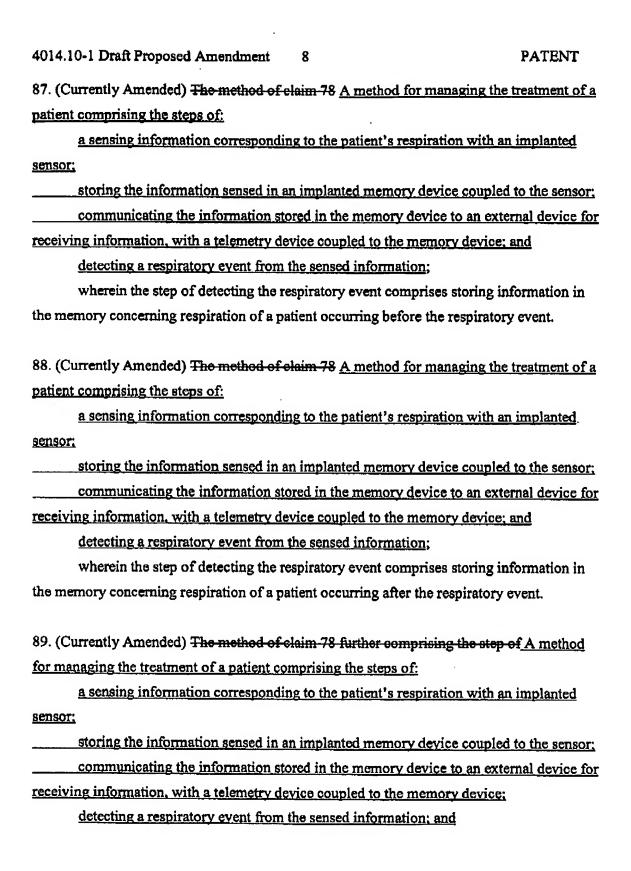
68. (Currently Amended) The method of claim 61 66 wherein the step of determining whether to electrically stimulate comprises detecting hypoventilation; and

further comprising the step of electrically stimulating the tissue to increase the diaphragm response.

69. -70 (Cancelled)

- 71. A method of controlling the respiration of a patient comprising the steps of:
 sensing information corresponding to a characteristic of a patient's respiration;
 comparing the characteristic to a desired characteristic; and
 electrically stimulating tissue of a patient to alter the patient's respiration to cause the
 characteristic to approach the desired characteristic.
- 72. The method of claim 71 wherein the characteristic comprises respiration rate.
- 73. The method of claim 71 wherein the characteristic comprises inspiration rate.
- 74. The method of claim 71 wherein the characteristic comprises exhalation rate.

75-86 (cancelled)



PATENT

receiving patient compliance information from the patient into a external memory of the external device.

- 90. The method of claim 89 wherein the step of receiving patient compliance information comprises receiving drug treatment compliance information.
- 91. The method of claim 89 further comprising the step of communicating uploaded information and patient compliance information to a health care provider through a remote interface.

92-93 (cancelled)

| 94. (Currently Amended) The method of claim 92 A method for managing respiration of a |
|---|
| patient comprising the steps of: |
| providing at least one electrode and coupling the at least one electrode to tissue of a |
| patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory |
| response: |
| provide stimulation to the tissue: |
| sensing respiratory response to adjust parameters of the stimulation to elicit a desired |
| respiratory response: |

wherein the stimulation comprises a burst of pulses and further comprising the step of adjust frequency of the pulses to elicit the desired response.

sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response:

| 4014.10-1 Draft Proposed Amendment 10 PATENT |
|---|
| wherein the stimulation comprises a burst of pulses and further comprising the step o |
| adjust pulse width of the pulses to elicit the desired response. |
| |
| 96. (Currently Amended) The method of claim 92 A method for managing respiration of a |
| patient comprising the steps of: |
| providing at least one electrode and coupling the at least one electrode to tissue of a |
| patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory |
| response; |
| provide stimulation to the tissue: |
| sensing respiratory response to adjust parameters of the stimulation to elicit a desired |
| respiratory response: |
| wherein the stimulation comprises a burst of pulses and further comprising the step of |
| adjusting duration of the pulses to elicit the desired result. |
| · |
| 97. (Currently Amended) A method for managing respiration of a patient comprising the |
| steps of: |
| providing at least one electrode and coupling the at least one electrode to tissue of a |
| patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory |
| response: |
| provide stimulation to the tissue; |
| sensing respiratory response to adjust parameters of the stimulation to elicit a desired |
| respiratory response; and |
| The method of claim 92 further comprising the step of adjusting stimulation to control |
| tidal volume of a respiratory cycle. |
| |
| 98. (Currently Amended)The method of claim 92 further comprising the step of |
| A method for managing respiration of a patient comprising the steps of: |
| providing at least one electrode and coupling the at least one electrode to tissue of a |
| patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory |

response;

| 4014.10-1 Draπ Proposed Amendment | 11 | PAIBNI |
|--|--------------------------------------|-----------------------|
| provide stimulation to the tissue: | | |
| sensing respiratory response to adj | ust parameters of the stimulation | to elicit a desired |
| respiratory response: and | | |
| adjusting stimulation to control ins | spiration rate. | |
| 99 (Currently Amended). The method of | iclaim 92 further comprising the s | ten of A method |
| for managing respiration of a patient com | | top or <u>armound</u> |
| providing at least one electrode an | | de to tissue of a |
| patient's body whereby electrical stimulat | • | |
| response; | | |
| provide stimulation to the tissue: | | |
| sensing respiratory response to adj | ust parameters of the stimulation | to elicit a desired |
| respiratory response; and | | |
| adjusting stimulation to control ex | halation rate. | |
| 100. (new) A device for managing respi | ration of a patient comprising: | |
| at least one electrode configured to | be coupled to tissue of a patient' | s body; and |
| a stimulation pulse generator confi | gured to deliver electrical stimula | tion to the tissue |
| through the at least one electrode to thereb | | |
| comprising a respiration waveform having | g an inspiration portion and an exh | alation portion; |
| wherein the stimulation pulse gene | rator is configured to control at le | ast one of said |
| inspiration portion and expiration portion | | |
| 101. (new) The device of claim 100 wher rate of inspiration. | ein the pulse generator is configur | ed to control the |
| 102. (new) The device of claim 100 wher | ein the pulse generator is configur | red to control the |

rate of exhalation.

PATENT

103. (new) The device of claim 100 further comprising a sensor configured to sense information corresponding to the respiration waveform of a patient's respiration; and

a responsive device coupled to the stimulation pulse generator, the responsive device being configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode to control a parameter of a respiration waveform of a subsequent respiration cycle.

- 104. (new) The device of claim 103 wherein the parameter is inspiration rate.
- 105. (new) The device of claim 103 wherein the parameter is exhalation rate.
- 106. (new) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the respiration waveform to control the partial pressure of carbon dioxide of the patient's blood.
- 107 (new) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the respiration waveform to control the level of oxygen in the patient's blood.
- 108. (new) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the inspiration time.
- 109. (new) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the inspiration amplitude.
- 110. (new) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the exhalation time.
- 111. (new) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the exhalation amplitude.

13

PATENT

- 112. (new) The device of claim 100 further comprising an apnea detector coupled to the sensor and configured to detect an apnea event.
- 113. (new) A method for controlling the partial pressure of carbon dioxide of blood of a patient comprising the steps of:

providing at least one electrode coupled to tissue of a patient's body; and a stimulation pulse generator configured to deliver electrical stimulation to the tissue through the at least one electrode:

eliciting a diaphragm respiratory response comprising a respiration waveform having an inspiration portion and an exhalation portion;

controlling at least one of said inspiration portion and expiration portion of the respiration waveform.

114. (new) A method of treating central sleep apnea comprising:

controlling partial pressure of carbon dioxide of blood of a patient by:

providing at least one electrode coupled to tissue of a patient's body; and
a stimulation pulse generator configured to deliver electrical stimulation to the tissue
through the at least one electrode:

eliciting a diaphragm respiratory response comprising a respiration waveform having an inspiration portion and an exhalation portion;

controlling at least one of said inspiration portion and expiration portion of the respiration waveform.

115. (new) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body;
and a stimulation pulse generator configured to deliver electrical stimulation through
the at least one electrode to the tissue to thereby elicit a diaphragm respiratory response;
a sensor configured to sense information corresponding to the patient's respiration:

PATENT

a hyperventilation detector coupled to the sensor configured to determine a hyperventilation event based at least in part on the sensed information;

14

an implantable memory device coupled to the sensor configured to store the information sensed; and

a telemetry device coupled to the memory device configured to communicate the information stored in the memory to an external device further comprising a processor coupled to the memory device and to the sensor, wherein the external device is configured to communicate to the patient to comply with medication requirements in response to determination of at least one hyperventilation event.

116. (new) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body; and
a stimulation pulse generator configured to deliver electrical stimulation to the tissue
through the at least one electrode to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration;

a responsive device coupled to the at least one electrode, the responsive device being configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode to adjust stimulation delivered through the at least one electrode based upon information sensed by the sensor, to elicit a respiratory response substantially similar to a predetermined respiratory waveform.

- 117. (new) The device of claim 116 wherein the predetermined respiratory waveform comprises an intrinsic respiratory waveform for the patient.
- 118. (new) The device of claim 5 wherein the responsive device is configured to adjust stimulation delivered to said at least one electrode to manipulate inspiration rate.
- 119. (new) The device of claim 118 wherein the responsive device is configured to adjust stimulation delivered to said at least one electrode to manipulate inspiration duration.

15

PATENT

- 120. (new) The device of claim 119 wherein the responsive device is configured to induce a slower inspiration rate with respect to an intrinsic inspiration rate and a longer inspiration duration with respect to an intrinsic inspiration duration.
- 121. (new) The device of claim 5 wherein the responsive device is configured to manipulate an inspiration waveform of an inspiration cycle to manipulate blood PCO₂.
- 122. (new) The device of claim 5 wherein the responsive device is configured to manipulate the respiration waveform to control the level of oxygen in the patient's blood.
- 123. (new) The device of claim 6 wherein the responsive device is configured to adjust stimulation delivered to said at least one electrode to manipulate exhalation rate.